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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,786	01/04/2002	Yasutaka Igari	074129-0492	7236

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/019,786	IGARI ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-15 and 20-23* is/are rejected.

7)☒ Claim(s) *16-19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment/Arguments

Applicant's amendments and arguments filed June 6, 2006 and resubmitted on September 20, 2006 are acknowledged and have been fully considered. It is noted that Applicant had provided the stamped PTO mailroom receipt dated for the originally submitted response.

Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has provided a certified English translation of the foreign priority document, and thus the rejection under 35 USC § 102(a) is withdrawn.

Respectfully, Applicant appears to have addressed the examiner's claim objection (*Office Action, page 3*) in response to the 35 USC 112 2nd rejection set forth (*Remarks, page 9*), and thus has not addressed the rejection as set forth. However, in view of the amendments to the claims, the rejection is withdrawn.

Claim 21 is objected to for the following informalities: While it is clear from Applicant's arguments that the composition of claim 3 is present in each of the therapeutic, prophylactic and contraceptive agents, the claim should be amended to more clearly indicate such. In the present form, the claim could be reasonably interpreted broadly to embrace two separate inventions (a) a therapeutic or prophylactic and (b) a contraceptive, where the contraceptive is the only element which requires the composition of claim 3, particularly since the claim recites the passive "containing" which can be reasonably construed to modify only the contraceptive. To more clearly define the invention, Applicant is suggested to amend the claim to recite, "wherein said prophylactic, therapeutic or contraceptive contains a sustained release composition according to claim 3." Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 remains rejected, for the reasons of record and those set forth below, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic agents or a contraceptive or a prophylactic for dysmenorrhea, does not reasonably provide enablement for other prophylactic agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

At the outset, the examiner agrees with Applicant's interpretation of the enabled/not enabled subject matter (*Remarks, page 8*).

Applicant argues that because the art explains a functional mechanism for LH-RH, e.g. leuprorelin, one of ordinary skill in the art would consider the agent effective against all recited indications. (*citing Pereti et al, Remarks, page 9*).

Respectfully, the examiner disagrees. The art clearly recognizes that many of the conditions cannot be prevented, and prophylaxis is prevention, as set forth previously (and below). Thus, one would not consider the full scope of the claims to be enabled and one would be burdened with undue experimentation to make the compounds which are prophylactics as claimed.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a prophylactic or therapeutic agent against prostate cancer, prostate hyperplasia, endometriosis, hysteromyoma, metrofibroma, precocious puberty, mammary cancer, or a contraceptive. Thus, the claims taken together with the specification imply the composition containing an LHRH derivative will treat or prevent all of the conditions, as well as act as a contraceptive.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Hysteromyoma and metrofibroma cannot be prevented (*see Uterine fibroids*, page 4). Early puberty (precocious puberty) is "often unpreventable" (*see Early puberty*, page 2). Prostate hyperplasia cannot be prevented (*see BPH*, page 4), nor can prostate cancer (*see Prostate Cancer*, page 3). Endometriosis is unpreventable as is breast cancer (*see Breast Cancer*, page 2).

Since the means for prevention of these conditions remains largely unsolved, means for making a pharmaceutical that is a prophylactic is highly unpredictable.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

Applicant have reasonably demonstrated/disclosed that the claimed compound is useful as a therapeutic agent for treating the recited conditions, as well as being a contraceptive. The art recognizes that contraceptives are used as preventative treatments (prophylactics) for dysmenorrheal. However, the claims also encompass using the claimed compound to prevent the prostate cancer, prostate hyperplasia, endometriosis, hysteromyoma, metrofibroma, precocious puberty and mammary cancer, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the terms "prophylactic" and "prevent" are an defined to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) – including preventing such disorders as prostate cancer, prostate hyperplasia, endometriosis, hysteromyoma, metrofibroma, precocious puberty and mammary cancer, which are clearly not recognized in the medical art as being a totally preventable condition.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above with regards to the inability to prevent the conditions and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make a prophylactic for the recited conditions, commensurate with the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-15 and 20-23 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U. S. Patent No. 6,740,634 B1 (SAIKAWA). Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons of record, and those set forth below.

Applicant argues that the Saikawa does not teach or suggest the product with the range of the weight average molecular weight (WAMW) as claimed.

Respectfully, the examiner disagrees. The polymers of Saikawa are of an overlapping, if not commensurate scope with the instantly claimed polymers. The instant claims and the claims of Saikawa require the same WAMW of the polymer portion and have the same composition of lactic acid/glycolic acid as well as the same μmol range per unit mass of terminal carboxyl groups.

Saikawa teaches a sustained release composition comprising a hydroxynaphthoic acid, a PLA-PGA polymer and a physiological active substance (claim 5), where the PLA/PGA ratio is 100/0 to 40/60 % (claim 6), is 100/0 (claim 7), where the WAMW of the polymer is 3,000-100,000 (claim 8), and 20,000 to 50,000 (claim 9) and where the amount of terminal carboxyl groups is 50-90 μmol (claim 11).

Saikawa teaches that the hydroxynaphthoic acid is 3-hydroxy-2-naphthoic acid (claim 3). Saikawa teaches that there are only 14 isomers of the naphthoic acid and that any one could be used, noting that the 3-hydroxy-2-naphthoic acid, 1-hydroxy-2-naphthoic acid, and 2-hydroxy-1-naphthoic acid are preferred (column 5, lines 40-46 and column 6, lines 1-3). Because there are so few members of the hydroxynaphthoic acid family explicitly recited, one could envisage each member individually.

Saikawa teaches that the pharmacologically active substance is an LHRH derivative (claims 2 and 10), at a ratio of 3:4 to 4:3 with the hydroxynaphthoic acid (claim 12), wihere the content of the LHRH derivative is 14 to 24 % (w/w) (claim 13), and where the physiologically active substance is slightly water soluble or water soluble (claim 14). Saikawa teaches that the composition is intended for injection (claim 15).

Saikawa teaches that the compound is used in the treatment of prostatic cancer, prostatic hypertrophy, endometriosis, hysteromyoma, metrofibroma, precocious puberty, dysmenorrhea, or breast cancer (claim 16) or to reduce fertility (claim 18).

Claims 1-3, 5-15 and 20-23 are directed to an invention not patentably distinct from claims 1-18 of commonly assigned SAIKAWA, for the reasons set forth *supra*.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300).

Commonly assigned SAIKAWA, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Allowable Subject Matter

Claims 16-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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